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MAY 20 1997

Summary of "ProSpore Self-contained Biological Indicator" for steam sterilization at 121°C

K971432

Submitter:	Raven Biological Laboratories, Inc. 5017 Leavenworth Street Omaha, NE 68106 (402) 556-6690 (402) 556-4722 FAX
Contact:	Russ Nyberg Production Microbiologist
Prepared on:	20 June 1996
Device name:	ProSpore® self-contained biological indicator
Classification:	Class II medical device, General Hospital
Predicate Devices (legally marketed)	Kilt™ (BBL) SporView™ (SPSmedical)
Predicate Devices 510(k) number:	Kilit™(BBL) - Grandfather In* SporView™ (SPSmedical) K905425

Description

ProSpore® is a self-contained biological indicator used for determining the efficiency of a 121°C steam sterilization cycle. The device is a *Bacillus* stearothermophilus in a recovery medium of Tryptic Soy Broth with Bromocresol purple, a pH indicator.

Specifications

1) **BI**

Microorganism: *Bacillus stearothermophilus* (ATCC # 7953)

Population: 1.0×10^5 - 4.0×10^5 cfu/unit

Resistance Characteristics: (for saturated steam at 121°C)

D-value: (determined using Spearman - Karber method on pages 43-50).

Survival time: (USP XXII, p. 204 - Attachment #9)
=[min] labeled D-value x ($\log_{10}$ labeled spore count per carrier -2)
Kill time: (USP XXII, p.204 - Attachment #9))
=[max] labeled D-value x ($\log_{10}$ labeled spore count per carrier +4)

Incubation period: 7 days

2) Components

Ampule: USP type 1, 4-ml flame-seal flint glass ampule

Culture/recovery medium: 10 ml of Bromocresol Purple (BCP) stock solution to each liter of Trypticase® Soy Broth (TSB), adjusted to a pH of 7.0 with Sodium Hydroxide (NaOH) and/or Hydrochloric Acid (HCL

nutrient: Trypticase® Soy Broth powder (Becton Dickinson), as per manufacturer's instructions

neutralizers: Sodium Hydroxide (NaOH) and Hydrochloric Acid (HCL)
pH indicator: Bromocresol Purple (4 grams BCP powder to each liter of deionized distilled water)

Operational Principles

The ProSpore® ampule is placed with a load in the sterilization chamber, and subjected to a normal steam sterilization cycle. The ampule is then removed and cooled to room temperature. Next, the processed ampule and an unprocessed (control) ampule are placed in incubation for a period of 7 days at a temperature favorable for growth (55^0 - 60^0 C, for *B. stearothermophilus)*.

During incubation, the available food supply (TSB) and temperature promote growth of viable spore. The growth process may be accompanied by turbidity and/or a release of acidic waste by products which reduce the pH level of the surrounding medium. Bromocresol purple reacts to this reduction by changing in color to or toward yellow.

Within 7 days, growth will become evident by a change in color from purple to/toward yellow and/or turbidity in the test ampule. This may be interpreted as a failure to meet the conditions necessary for sterilization, provided these signs are present in the control ampule.

Statement of similarity to legally marketed (predicate) devices:

ProSpore® is similar in composition and function to Kilt™ and SporView™, as these devices, like ProSpore® combines *Bacillus stearothermophilus* spores and a recovery medium (combined

with a pH indicator) in a flame-sealed glass ampule for use in determining the efficacy of steam sterilization cycles.

Clinical Tests:
No clinical tests have been performed.

Discussion of results from nonclinical tests:

Testing was performed to validate the labeled claims and performance characteristics for ProSpore®. These included studies on the labeled incubation period, recovery of damaged spores, the effect of the pH indicator on the recovery of injured spores, and the stability of population and D-value after a real time of one year. Test results confirmed that the tested samples conformed to the labeled claims.

Statement of safety and effectiveness:

Based on similar claims and design, and results from the nonclinical studies mentioned above, the ProSpore® biological indicator has been determined to be substantially equivalent and, therefore, as safe and effective to the legally marketed devices Kilt™ and SporView™.

*Kilit™(BBL) does not have a 510 (k) number. It was marketed under the grandfather clause, which exempts devices in commercial distribution prior to May 28, 1976. We have obtained the results of the Trademarkscan search of the U.S. Patent Office trademark filing showing that the product was introduced into commerce on June 8, 1955 (Attachment 10). The FDA # is M452998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Mr. Kerrie Groff
Quality Assurance Manager
Raven Biological laboratories, Incorporated
P.O. Box 6408
5017 Leavenworth Street
Omaha, Nebraska 68106

Re: K971432
Trade Name: Prospore
Regulatory Class: II
Product Code: FRC
Dated: April 15, 1997
Received: April 17, 1997

Dear Mr. Groff:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: ProSpore®

Indications For Use:

ProSpore® is a biological sterilization process indicator for steam sterilization at 121°C is a device intended for use by a health care provider to accompany products being sterilized through a steam sterilization procedure and to monitor adequacy of sterilization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Qian S. Lin

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K971432

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)